



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

J. Christopher Prue, RPh, MBA
Senior Director, U.S. Regulatory Affairs
Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901

RE: NDA # 20-553
OxyContin® (oxycodone hydrochloride) Controlled-Release Tablets
MACMIS # 12058

Dear Mr. Prue:

This letter responds to Purdue Pharma's submission, dated October 29, 2003 requesting comments on proposed promotional materials for OxyContin® (oxycodone hydrochloride) Controlled-Release Tablets. This submission included the following:

1. OxyContin 10 / 20 mg Visual Aid (Artwork No. A7429)
2. Three Case Studies to be inserted in the referenced Visual Aid:
 - "Osteoarthritis - Pain 1" (Artwork No. A7448)
 - "Osteoarthritis - Pain 2" (Artwork No. A7449)
 - "Rheumatoid Arthritis Pain" (Artwork No. A7450)
3. Percussion Hammer, bubble wrapped with package insert (No Artwork No.)

The Division of Drug Marketing, Advertising, and Communications (DDMAC) in consultation with the Division of Anesthetic, Critical Care, and Addiction Drug Products (DACADP), has reviewed the proposed promotional materials and offers the following comments by promotional item. Our comments should be applied to these and future promotional materials for OxyContin that include the same or similar claims or representations.

OxyContin 10/ 20 mg Visual Aid**Context**

On page 4, you present a figure entitled "Consistent plasma levels over 12 hours." For consistency with the approved product labeling (PL), we suggest that you also prominently present the material fact "Data obtained while volunteers received naltrexone which can enhance absorption" in conjunction with the aforementioned figure.

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Omission of Important Risk Information

On page 5, you present the claim "OxyContin is not for everyone" along with several bullets describing situations where OxyContin use is inappropriate. This presentation is misleading because you fail to present important risk information that describes patient populations where OxyContin use is contraindicated. We suggest that you prominently present OxyContin's contraindications in their entirety along with the aforementioned presentation. Please refer to your Detail Aid submission dated July 10, 2003, where you included OxyContin's contraindications under the header "OxyContin is not for everyone."

Three Case Studies

"Osteoarthritis -- Pain 1"

Broadening of Indication

You present the claim "Persistent pain due to osteoarthritis." This claim is misleading because it implies that all patients with persistent pain due to osteoarthritis are appropriate candidates for OxyContin when such is not the case. We note that you present OxyContin's full indication on the other side of the case study, however, that does not remedy this misleading claim. Please refer to our comments dated March 26, 2003, regarding a similar issue.

Misleading Dosage and Administration Claims

You present claims describing a change in the patient's (i.e., G.I.) drug regimen of hydrocodone/acetaminophen 5/500 mg 2 tablets q6h to OxyContin 20 mg q12h. This presentation is misleading because it suggests a higher dosage of OxyContin than is recommended (i.e., 10 mg q12h) based on the conversion guidelines put forth in the Dosage and Administration section of the PI. Please refer to our comments dated March 26, 2003, regarding a similar issue.

Unsubstantiated Superiority Claims

Your proposed case study presents the history of a patient who was unable to tolerate treatment with an NSAID and was started on OxyContin because the patient's "pain ratings decreased but patient complained of inadequate duration of analgesia" with two hydrocodone/acetaminophen (5/500 mg) tablets every 6 hours. The patient was started on OxyContin 20 mg every 12 hours. A 0-10 pain scale is presented and labeled "Initial pain scale ratings" and is marked with an arrow extending from 8-10. Another 0-10 pain scale labeled "Pain ratings at follow-up" is marked with an arrow extending from 0-3. This presentation is misleading because it implies that OxyContin decreased the patient's level of pain from 8-10 to 0-3, thereby implying that OxyContin is more effective than hydrocodone/acetaminophen when such has not been demonstrated by substantial evidence. Furthermore, this presentation is misleading because it overstates OxyContin's effectiveness, thereby implying that all patients will experience this level of pain relief when such has not been demonstrated.

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Minimization of Risk

You describe the patient in this case study as "G.L., 52-year-old male, truck driver." This presentation is misleading because you omit important risk information, thereby minimizing the risks associated with OxyContin. Specifically, you fail to present information from the PI that states "OxyContin may impair mental and/or physical ability required for the performance of potentially hazardous tasks (e.g., driving, operating heavy machinery)." DDMAC suggests including this material fact prominently with this presentation to avoid a misleading message.

Context

You present claims suggesting specific dosing. For consistency with the Dosage and Administration section of the PI, we suggest that you prominently add the material fact "OxyContin should be individually titrated to a dose that provides adequate analgesia and minimizes side effects."

"Osteoarthritis - Pain 2" (Artwork No. A7449)

The above comments addressed to the "Osteoarthritis - Pain 1" Case Study should also be applied to this promotional piece. In addition, DDMAC notes the following:

Unsubstantiated Function Claim

You present the claim "Patient has difficulty performing daily activities, such as shopping and housecleaning" under the header "Clinical history and presentation" followed by the claim "Patient activity level improved, is able to walk at the mall with her husband" under the header "Outcome." This presentation is misleading because it implies that OxyContin improves patients' abilities to perform daily activities when such is not supported by substantial evidence.

"Rheumatoid Arthritis Pain" (Artwork No. A7450)

The above comments addressed to the "Osteoarthritis - Pain 1" and "Osteoarthritis - Pain 2" Case Studies should also be applied to this promotional piece. In addition, DDMAC offers the following comments:

Misleading Efficacy Presentation

You present a profile entitled "Persistent Pain Due To Rheumatoid Arthritis" along with two visuals entitled "Initial pain scale ratings" and "Pain ratings at follow-up." This patient profile is misleading because it implies that the efficacy of OxyContin has been established in a Rheumatoid Arthritis Pain Model when such is not the case.

Unsubstantiated Superiority Claims

Your proposed case study presents the history of a patient who was taking two oxycodone/acetaminophen (5/325mg) tablets every 6 hours because the patient's "pain increased." The patient's medication was changed to OxyContin 20 mg every 12 hours. A 0-10 pain scale is presented and

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labeled "Initial pain scale ratings" and is marked with an arrow extending from 7-8. Another 0-10 pain scale labeled "Pain ratings at follow-up" is marked with an arrow extending from 0-2. This presentation is misleading because it implies that OxyContin decreased the patient's level of pain from 7-8 to 0-2, thereby implying that OxyContin is more effective than oxycodone/ acetaminophen when such has not been demonstrated by substantial evidence. Furthermore, this presentation is misleading because it overstates OxyContin's effectiveness, thereby implying that all patients will experience this level of pain relief when such has not been demonstrated.

Percussion Hammer, bubble wrapped with package insert

We have reviewed the proposed Percussion Hammer and have no comments at this time.

If you have any questions, please contact me by facsimile (301) 594-6771, or write to me at the Division of Drug Marketing, Advertising, and Communications, HFD-42, Room 3B-45, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 12058 in addition to the NDA number.

Sincerely,

(See appended electronic signature page)

Brenda Marques, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

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/s/

Brenda Marques
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TOTAL P.06

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